



PATENT  
Customer No. 22,852  
Attorney Docket No. 07579.0015-01000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: )  
Graham Edmund KELLY et al. ) Group Art Unit: 1623  
Application No.: 10/600,004 ) Examiner: Not Yet Assigned  
Filing Date: June 18, 2003 ) Confirmation No. 6037  
For: CARDIOVASCULAR AND BONE )  
TREATMENT USING ISOFLAVONES )

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**UPDATED NOTICE REGARDING RELATED LITIGATION**

Applicants hereby submit this Updated Notice Regarding Related Litigation to the U.S. Patent and Trademark Office to inform the Office of the current status of the Solae I and Solae II litigations. The present application, U.S. Serial No. 10/600,004, filed June 18, 2003, is a continuation of U.S. application Serial No. 09/914,035, filed as PCT/AU00/00384 on April 27, 2000, which entered the national stage on December 10, 2001. Although the instant application and the patents in suit do not share a common specification or overlapping claims to priority, in the utmost caution, the Applicants submit this notice in the event that the disclosures in the respective specifications would ever be considered related. Application Serial Nos. 10/600,004 and 09/914,035 are assigned to Novogen Pty. Ltd. ("Novogen").

Applicants previously submitted a Notice Regarding Related Litigation informing the Office that on June 3, 2003, Solae, L.L.C. ("Solae") filed a Complaint alleging that Archer

Daniels Midland Company (“ADM”) and Amerifit Nutrition, Inc. (“Amerifit”) infringe at least one claim of U.S. Patent No. 6,562,380 (“the ‘380 patent”). The case, Civil Case No. 4:03-CV-00732-HEA, was filed in U.S. District Court for the Eastern District of Missouri (“Solae I”). The ‘380 patent issued from U.S. application Serial No. 08/910,837 on May 13, 2003, and was originally filed on August 13, 1997, as a continuation of U.S. Application Serial No. 08/338,567, filed January 12, 1995, now U.S. Patent No. 5,830,887.

Applicants also informed the Office that on November 4, 2003, Solae filed a separate Complaint alleging that ADM and Amerifit infringe at least one claim of the U.S. Patent No. 6,642,212 B1 (“the ‘212 patent”). The case, Civil Case No. 4:03-CV-01595 RWS, was filed in U.S. District Court for the Eastern District of Missouri (“Solae II”). The ‘212 patent issued from U.S. application Serial No. 09/421,069 on November 4, 2003, and was originally filed on October 19, 1999, as a continuation of U.S. application Serial No. 08/910,837, filed August 13, 1997, now U.S. Patent No. 6,562,380 B1.

### **SOLAE I**

We highlight the following events in the Solae I litigation, which have occurred since December 23, 2003, the date of our previous Notice. On March 11, 2004, the Court issued a Memorandum and Order denying defendants ADM and Amerifit’s Motions to Dismiss for Lack of Standing and Failure to Join an Indispensable Party. On March 18, 2004, Defendants ADM and Amerifit filed a Motion for Reconsideration of this order.

On April 1, 2004, defendants ADM and Amerifit both filed Answers and Counter Claims to Plaintiff’s Complaint. In these Answers ADM and Amerifit denied the allegations, contained in Solae’s complaint. ADM and Amerifit asserted the affirmative defenses of invalidity and non-infringement of the ‘380 and the ‘212 patents. ADM and Amerifit also presented counterclaims

asking to declare the '380 and the '212 patents invalid and non-infringed. On April 21, 2004, plaintiff Solae filed Replies to the Answers and Counterclaims of both defendants, ADM and Amerifit. In these Replies Solae denied the defendants' allegations.

Further to this Notice, the Applicants attach: the Memorandum and Order Denying ADM's Motion To Dismiss For Lack Of Standing And Failure To Join An Indispensable Party; Defendants Archer Daniels Midland Company And Amerifit Nutrition, Inc.'s Motion For Reconsideration; Defendant, Amerifit Nutrition, Inc.'s Answer and Counter Claims to Plaintiff's Complaint; Defendant, Archer Daniels Midland Company's Answer And Counter Claims to Plaintiff's Complaint; Plaintiff's Reply to Answer and Counterclaims of Defendant Archer Daniels Midland Company; Plaintiff's Reply to Answer and Counterclaims of Defendant Amerifit Nutrition, Inc.; and the docket for this case, current as of April 23, 2004.

### SOLAE II

We highlight the following events in the Solae II litigation, which have occurred since December 23, 2003, the date of our previous Notice. On December 29, 2003, Solae filed a First Supplemental Complaint against all defendants alleging that ADM and Amerifit infringe at least one claim of the '212 patent. In this Complaint Solae also alleges that defendants infringe at least one claim of U.S. Patent No. 6,664,382 ("the '382 Patent"). On January 29, 2004, plaintiff Solae filed a Second Supplemental Complaint alleging that ADM and Amerifit infringe at least one claim of the '212 patent and the '382 patent. In this Complaint Solae added infringement of U.S. Patent No. 6,680,381 ("the '381 patent") to its allegations.

On April 1, 2004, defendants ADM and Amerifit both filed Answers and Counter Claims to Plaintiff's Second Supplemental Complaint. In these Answers ADM and Amerifit denied the allegations contained in Solae's second supplemental complaint. ADM and Amerifit asserted the

affirmative defenses of invalidity and non-infringement of the '212 patent, the '382 patent and the '381 patent. ADM and Amerifit also presented counterclaims asking to declare the '212 patent, the '382 patent, and the '381 patent invalid and non-infringed. On April 21, 2004, plaintiff Solae filed Replies to the Answers and Counterclaims of both defendants, ADM and Amerifit. In these Replies Solae denied the defendants' allegations.

Further to this Notice, the Applicants attach Plaintiff, Solae, LLC's First Supplemental Complaint; Plaintiff, Solae, LLC's Second Supplemental Complaint; Defendant, Amerifit Nutrition, Inc.'s Answer And Counter Claims to Plaintiff's Second Supplemental Complaint; Defendant, Archer Daniels Midland Company's Answer and Counter Claims to Plaintiff's Second Supplemental Complaint; Plaintiff's Reply to Answer and Counterclaims of Defendant Archer Daniels Midland Company; Plaintiff's Reply to Answer and Counterclaims of Defendant Amerifit Nutrition, Inc.; and the docket for this case, current as of April 23, 2004.

**REMARKS**

As stated above, the present application and the patents in suit do not share a common specification or overlapping claims to priority although they do relate to isoflavones and are all assigned to Novogen Pty. Ltd. Nevertheless, to avoid even the appearance of impropriety, Applicants submit this Notice in the event that the disclosures in the respective specifications would ever be considered related.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: April 30, 2004

By: Deborah J. Acker  
Deborah J. Acker  
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